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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,845	10/23/2001	Shlomo Ben-Haim	IMP031-228740	1690
54042 7590 07/18/2007 WOLF, BLOCK, SHORR AND SOLIS-COHEN LLP 250 PARK AVENUE 10TH FLOOR NEW YORK, NY 10177			EXAMINER LAYNO, CARL HERNANDZ	
			ART UNIT 3766	PAPER NUMBER
			MAIL DATE 07/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No. 10/039,845	Applicant(s) BEN-HAIM ET AL.	
	Examiner Carl H. Layno	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/563,544.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/23/01, 2/24/04, 5/6/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for priority as a Continuation of U.S. Application 09/563,544, filed on May 1, 2000, now U.S. Patent No. 6,363,279, which is a Continuation of U.S. Application 09/101,723, filed on August 13, 1998, now U.S. Patent No. 6,317,631, which is a 371 of PCT/IL97/00012, filed on January 8, 1997, which claims benefit of priority filing from U.S. Provisional Applications: 60/009,769 filed January 11, 1996, 60/011,117, filed February 5, 1996, and 60/026,392, filed September 16, 1996.

Information Disclosure Statement

2. Acknowledgment is made of applicant's Information Disclosure Statements (PTO-1449s), which were received by the Office on October 23, 2001, February 24, 2004, and May 6, 2005.

Drawings

3. Applicant's formal drawings were received by the Office on October 23, 2001. These drawings have been approved by the Examiner.

Specification

4. The disclosure is objected to because of the following informalities:

-p.1, paragraph 1, of the specification should be updated to reflect that U.S. Application Serial No. 09/563,544 is now U.S Patent No. 6,363,279 and that U.S Application Serial No. 09/101,723 is now U.S Patent No. 6,317,631.

Appropriate correction is required.

Claim Objections

5. Claims 6 and 7 are objected to under 37 CFR 1.75(c) for failing to further limit a parent claim. As written, claims 6 and 7 depend from canceled claims 63 and 64, which are no longer present in the application. To correct this problem, the Examiner recommends changing the claim dependencies to depend from claim 5. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

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reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 3-7 are rejected under 35 U.S.C. 102(b) as being anticipated by the Fromer et al article "Ultrarapid Subthreshold Stimulation for Termination of Atrioventricular Node Reentrant Tachycardia" (cited prior art).

In regard to claims 3-5, Applicant's cited prior art article "Ultrarapid Subthreshold Stimulation for Termination of Atrioventricular Node Reentrant Tachycardia" by Fromer et al appears to read upon applicant's method and apparatus claims. The article recites that subthreshold stimulation pulses are applied to the heart at "various atrial sites" (p.879, Methods, lines 3-4) to terminate sustained atrioventricular (AV) node reentrant tachycardias. The subthreshold stimuli prolong the effective refractory periods thereby inhibiting the heart's response to "subsequent suprathreshold extrastimuli" and enabling "termination of ventricular tachycardia and reciprocating tachycardia" (p.879, Background, lines 1-4).

In regard to claim 6, the Examiner is taking the position that application of stimulation pulses to the heart would inherently generate an electric field.

In regard to claim 7, Fromer et al states that at least one electrode was used for generating the non-excitatory signal since the stimulation electrode that terminated a tachycardia was located at either "the low right atrial septum...or proximal the coronary sinus" (p.881, col.2, lines 10-14).

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8. Claims 3-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Hill et al (US 5,411,531).

In regard to claims 3-5, the Hill et al (US 5,411,531) patent describes an implantable heart pacemaker (Fig.2) and method of using, which include the delivery of non-excitatory pulse bursts (Figs.1A-1D) (e.g. **138, 142, 164**, etc.) to extend the AV pacing delay to “prevent the occurrence of PVC’s and to terminate or prevent induction of arrhythmias” (Abstract, lines 7-9). This would inherently reduce the reactivity of the heart chamber being stimulated. The pulse bursts are “not intended to induce depolarizations of the atrium or ventricles, and are delivered during the absolute refractory periods following the occurrence of depolarizations in the chamber to which they are synchronized” (col.3, lines 36-40).

In regard to claims 6 and 7, the Hill et al device includes dual purpose sensing/stimulation electrodes **612, 614, 618**, and **620** (Fig.3). The Examiner is taking the position that when generating pulse bursts to be applied to a patient’s heart, electric fields would inherently be generated.

9. Claims 1, 2, 8, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Taylor et al (US 5,913,876).

Although applicant claims benefit of priority filing to provisional applications 60/009,769, 60/011,117, and 60/026,392, the Examiner could not find any support in these claims directed at applying non-excitatory signals to a portion of the heart as a preliminary step before a surgical operation. The first appearance of this seems to have occurred in

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PCT/IL97/00012, filed 1/8/1997, (col.33, lines 40-52). Hence, the Examiner deems the Taylor et al '876 patent, with a priority filing date of February 20, 1996, to be a valid prior art reference.

In regard to claims 1 and 8, the Taylor et al (US 5,913,876) patent, cited by the applicant as prior art, describes an embodiment for an implantable vagal nerve stimulator (Fig.22) wherein one of the stimulation electrodes (clip #4) is located on a portion of the heart called the "cardiac plexus" (col.11, lines 50-55 – Fig.22). Stimulation pulses applied to the electrodes of Taylor et al are used to slow the heart down or temporarily stop it for a surgical operation (i.e. anastomosis) (Abstract – lines 9-13).

In regard to claims 2 and 9, stimulating the vagal nerve to slow the heart down would inherently cause a decrease in the output flow of blood from the heart.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

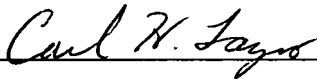
The Stroetmann et al (US 5,578,061) patent is cited for its pertinent use of non-excitatory parasympathetic nerve stimulation signals used to slow down the heart. It is unclear whether or not stimulation signals are applied to any portion of the heart.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CARL LAYNO
PRIMARY EXAMINER

CHL

7/16/2007